REMARKS

I. Status of Pending Claims

Claims 22, 25, 28-30, 32-39, 57, 58, 60-89, and 96 are pending in this application, with claims 22, 28, 29, 32, 33, 38, 57, 60, 61, 62, 70, and 84 being independent. In the Office Action dated January 4, 2007, the Examiner rejected each pending claim under 35 U.S.C. § 103(a) over Japanese Publication No. JP 08-257136 to Asano et al. ("Asano") in view of U.S. Patent No. 4,984,581 to Stice ("Stice") either alone, or further in view one or more of U.S. Patent No. 5,174,302 to Palmer ("Palmer"); U.S. Patent No. 5,947,940 to Beisel ("Beisel"), and U.S. Patent No. 4,763,647 to Gambale ("Gambale").

With this reply, Applicants have cancelled claim 97 and amended independent claim 32 to include the recitations of cancelled claim 97.

II. Request for Withdrawal of the Finality of the January 4, 2007, Office Action

In the Office Action dated July 7, 2006, the Examiner rejected each pending claim, except independent claim 32. Despite the fact that claim 32 was listed as being rejected on line six (6) of the Office Action Summary form PTOL-326 accompanying the July 7, 2006 Office Action, the content of the Office Action omitted any discussion of claim 32. Thus, no grounds of rejection were advanced for independent claim 32. Accordingly, Applicants did not amend claim 32 in their response of October 6, 2006. Instead, Applicant's requested clarification as to the status of claim 32 from the Examiner in response to their reply of October 6, 2006. Since no grounds of rejection were presented regarding claim 32, Applicants respectfully requested that, should the Examiner reject claim 32 in a forthcoming Office Action, such rejection be made non-final.

In explaining the basis for the finality of the January 4, 2007 Office Action, the Examiner stated that he "inadvertently left '32' out of the statement regarding which claims were rejected. However, each of the claim limitations present in claim 32 were addressed in section 3 of the Office Action." (January 4, 2007, Office Action p. 9). For at least the following reasons, Applicants dispute the propriety of making the January 4, 2007 Office Action final.

The Manual of Patent Examining Procedure sets forth that:

> Under present practice, second or any subsequent actions on the merits shall be final, **except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims** nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

M.P.E.P. § 706.07(a) (8th ed. Rev. August 2006), p. 700-82 (emphasis added). Since no ground for rejection of claim 32 was advanced in the Office Action of July 7, 2006, and since claim 32 was not amended in Applicants' response of October 6, 2006, the finality of the Office Action of January 4, 2007 is improper. The Examiner introduced a new ground of rejection for claim 32, which was not necessitated by an amendment. This violates M.P.E.P. § 706.07(a).

Moreover, the assertion that the recitations of claim 32 were addressed in section 3 of the Office Action does not establish the Examiner's required burden for rejecting a claim. Regarding a *prima facie* case of obviousness, "**[t]he initial burden is on the examiner** to provide some suggestion of the desirability of doing what the inventor has done." M.P.E.P. § 706.02(k) (8th ed. Rev. August 2006), p. 700-48, referencing *Ex Parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985) (emphasis added). That

burden is not met where an Examiner requires an Applicant to infer a rejection amongst a lengthy Office Action. Applicants should not be expected or required to reject their own claims.

Since the Examiner failed to set forth any grounds for rejection regarding claim 32 in the Office Action of July 7, 2006, Applicants respectfully request that the finality of the Office Action dated January 4, 2007, be withdrawn as impermissibly premature.

III. Applicants' Amendment to Claim 32 Should be Entered

If the finality of the January 4, 2007, Office Action is maintained, Applicants will have been deprived of their right to amend claim 32. Accordingly, Applicants request that the enclosed amendments to claim 32 be entered upon the filing of this Amendment. Since amended claim 32 merely represents the recitations of former claim 97, consideration of this amendment to claim 32 would not entail further search and consideration by the Examiner, especially if the Examiner's assertion is true that each claim limitation was addressed in the prior Office Action. At the very least, the amendment to claim 32 should be entered for purposes of appeal, as explained in M.P.E.P. § 714.13. III (8th ed. Rev. August 2006), p. 700-260.[1]

[1] For example, regarding procedures governing the entry of amendments after actions properly made final, the M.P.E.P. explains that "Examiners should indicate the status of each claim of record or proposed in the amendment, and which proposed claims would be entered on the filing of an appeal if filed in a separate paper. Whenever such an amendment is entered for appeal purposes, the examiner must indicate on the advisory action which individual rejection(s) set forth in the action from which the appeal was taken (e.g., the final rejection) would be used to reject the new or amended claim(s)." M.P.E.P. § 714.13. III (8th ed. Rev. August 2006), p. 700-260.

IV. Claims 22, 28, 29, 32, 33, 38, 57, 60-62, 70, and 84 Are Patentable in View of the Prior Art

In the Office Action of January 4, 2007, the Examiner rejected each of independent claims 22, 28, 29, 32, 33, 38, 57, 60-62, 70, and 84, asserting that each claim is obvious in view of the prior art. In rejecting these independent claims, the Examiner relied upon Asano as the primary reference in an obviousness rejection. As will be described in more detail below, neither Asano, nor any of the other cited art, either alone or in combination, adequately supports a prima facie case of obviousness.

Independent claim 22 recites, *inter alia*, a guide wire having an elongate core and a continuous coil. The coil has an inner diameter and an outer diameter and extends beyond the distal end of the core by a plurality of non-contacting turns of the coil. A polymeric tip extends from a distal portion of the coil. The tip connects to the core by a polymeric material provided within spaces between non-contacting adjacent turns of the coil such that the polymeric material encloses at least an area inside the inner diameter of the coil and up to the outer diameter of the coil. Claims 28, 29, 33, and 38 include similar recitations.

In addition, as amended, independent claim 32 recites, *inter alia*, a guide wire having an elongate core, comprised of a nickel-titanium, and a continuous coil. The coil has an inner diameter and an outer diameter and extends beyond the distal end of the core by a plurality of non-contacting turns of the coil. A polymeric tip extends from a distal portion of the coil. The tip connects to the core by a polymeric material provided within spaces between non-contacting adjacent turns of the coil such that the polymeric material encloses at least an area inside the inner diameter of the coil and up to the outer diameter of the coil.

Moreover, each of independent claims 57, 60-62, 70, and 84 recites, *inter alia*, a guide wire having an elongate core and a continuous coil that extends beyond the distal end of the core by a plurality of turns of the coil. The plurality of the turns include non-contacting adjacent turns defining spaces extending to an outer diameter of the adjacent turns. A polymeric tip extends from a distal portion of the coil. The tip connects to the core by a polymeric material that entirely fills said spaces between the adjacent turns of the coil.

For the reasons that follow, the cited references fail to teach or suggest, either alone or in combination, each and every recitation of these independent claims.

In the Office Action of January 4, 2007, the Examiner relies on the disclosure of FIG. 8 of Asano. More particularly, the Office Action relies on coil 21 and material 12 in FIG. 8 of Asano as allegedly corresponding to the claimed coil and polymeric tip. (See, e.g., January 4, 2007, Office Action under headings 3-6 and 8). Coil 21 disclosed in Asano, however, has adjacent turns that are in contact with each other with no spaces defined therebetween. Asano only teaches a coil having approximately six ***contacting*** adjacent turns mounted over a distal portion of a wire 11.

The Examiner concedes this deficiency of Asano on pages 3-6 and 8 of the January 4, 2006 Office Action, explaining that "Asano et al. fails to disclose the coil having a plurality of turns including non-contacting adjacent turns...." (January 4, 2007, Office Action, p. 3). The Examiner attempts to compensate for this deficiency in Asano by pointing to the disclosure of Gambale. In particular, page 5 of the Office Action provides that:

> Gambale discloses a guide wire having an elongate core and a coil surrounding a portion of the core. Gambale

> teaches varying the flexibility characteristics by providing the coil with a pitch that varies (Col. 3, lines 52-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Asano et al. to include a pitch that varies in order to arrive at a desired flexibility of the distal end region (Col. 3, lines 52-61). By modifying the pitch of the coil, spaces would be created between adjacent turns of the coil that would be filled with polymeric material (12) when immersed into the resin liquid [0032].

Applicants dispute this suggested modification and assert that one of ordinary skill in the art would not be motivated to alter the pitch of coil 21 as proposed for at least the following reasons. Based on a reading of the translation and abstract of Asano provided,[2] however, it is clear that the underlying purpose of the invention is to provide a guide wire with enhanced "radiopacity" for contrast during imaging. (See, e.g., paragraph [0007] of the machine translation). In reaching this goal, in one embodiment a coil 21 is provided solely to enhance adhesion of a radiopaque resin 12 to the tip of wire 11. (See paragraph [0032] of the translation). Specifically, the coil 21 is attached to the tip of wire 11 by soldering, and then the coil 21 is immersed in resin to adhere the resin film 12, which includes "radiopacity" material (see, e.g. paragraphs [0030] and [0032] of the machine translation), to the tip part 11a. Applicants can find no disclosure in Asano concerned with enhancing the flexibility of the guide wire.

The Examiner agrees that "Asano et al. fails to discuss enhancing the flexibility of the guide wire." (January 4, 2007, Office Action at pages 9-10.) To modify Asano's coil, however, the Examiner relies on Gambale's alleged teachings that spacing of a coil can

[2] The translation of Asano that accompanied the July 7, 2006 Office Action appears to be an machine translation and does not represent a precise literal translation of the disclosure, as evidenced, for example, by the extensive grammatical errors therein.

be modified to achieve a desired flexibility.

Even if one were motivated to increase the flexibility of the Asano guidewire 20, however, there is no basis to assert that one would have been motivated to alter the pitch of coil 21 to achieve such a result. For example, as seen in FIG. 8 of Asano, coil 21 includes approximately six contacting turns, only about two of which extend beyond the end of item 11. Accordingly, coil 21 extends along an extremely small portion of the guide wire 20. As such, altering the pitch of coil 21 would not result in appreciable change in flexibility for guide wire 20 of Asano. Coil 21 in FIG. 8 of Asano simply plays little or no role in controlling the flexibility of the guide wire 20. Instead, the coil 21 in the device of Asano serves an entirely different function than that of the coils 16 and 22 in Gambale. Coil 21 in Asano solely enhances adhesion of a radiopaque resin 12 to a select portion at the tip of wire 11. (See Asano at paragraph [0032] of the translation). Conversely, the outer and inner coils 16, 22 of Gambale each extends through significant lengths of the guide wire[3] and are configured to vary the flexibility characteristics of the disclosed guidewire.

Moreover, the flexibility of the Asano guide wire 20 likely is already controlled by virtue of the shape of portion 11a of the underlying wire 11. In other words, the flexibility of wire 20 is manipulated, if at all, through modification of the wire's cross-section rather than modification of the spacing along six turns of coil 21 that extend along only a very small portion of the device.

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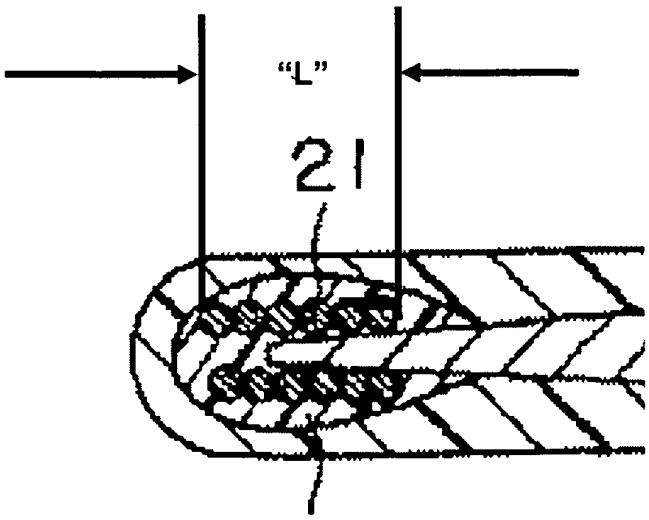
[3] FIGS. 1-2 of Gambale illustrate coils extending over a significant length of the guidewire. For example, region 12 is depicted as being approximately 25 to 30 cm long. (See Gambale at column 2, lines 67-68.) In addition, since FIGS. 1-2 are fragmentary views, the coils will extend through many more turns than depicted in FIGS. 1-2.

In addition, increasing the pitch of coil 21 would result in very few turns of coil 21. With less coil turns, the intended purpose of coil 21 is frustrated. That is, less coil turns will diminish the ability of coil 21 to adhere resin 12 to tip 11a, at least by virtue of less surface area on the coil 21. The suggested modification of the coil in the Asano guide wire therefore may render the coil unsuitable (or at least less suitable) for its intended purpose. See, *Tec Air, Inc. v. Denso Mfg. Michigan, Inc.*, 192 F.3d 1353, 1360, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) ("There is no suggestion to combine, however, if a reference teaches away from its combination with another source") (internal citations omitted).

The response to arguments section of the January 4, 2007 Office Action asserts that "modifying the pitch (i.e. spacing) of the coil does not equate to reducing the number of coils." (January 4, 2007, Office Action, p. 9). Modifying the coil pitch, however, either reduces the number of coils or, if not, lengthens the coil. The portion "L" from the annotated FIG. 8 of Asano depicted below shows the length of the coil. If the number of coils is lessened (i.e., if length "L" includes less turns), the ability of the coil 21 to adhere resin 12 to tip 11a is diminished, as mentioned.



Annotated FIG. 8 from Asano

And, one would not be motivated to lengthen coil 21. In contrast to the coils of Gambale, Asano's coil is solely concerned with enhancing adhesion of resin 12 at a discrete, very short length along the tip of wire 11. One would not want to lengthen the radiopaque resin portion and thereby lengthen coil 21 (i.e., increase the distance of length "L"), since it would extend the length of the guidewire portion exhibiting "radiopacity" for contrast during imaging. The enlarged area of radiopacity would diminish the precision with which the guidewire could be positioned under imaging control. With an enlarged area covered by resin 12, the operator will be less likely to precisely position a particular portion of the guidewire relative to specific internal patient anatomy.

Accordingly, for at least the reasons presented above, there is no motivation to modify the device of Asano with the device of Gambale. Applicants therefore submit that the cited references fail to teach or suggest, either alone or in combination, at least the features of a plurality of non-contacting turns of the coil extending beyond a distal end of a core and a polymeric material provided within spaces between adjacent non-contacting turns of the coil, as recited in independent claims 22, 28, 29, 32, 33 and 38. Therefore, for at least the reasons presented above, the cited prior art fails to teach or suggest the subject matter recited in claims 22, 28, 29, 32, 33 and 38, and all of the claims dependent thereon.

In addition, the cited references fail to teach or suggest, either alone or in combination, at least the features of a plurality of the turns including non-contacting adjacent turns defining spaces extending to an outer diameter of the adjacent turns, and

a polymeric tip that connects to the core by a polymeric material that entirely fills said spaces between the adjacent turns of the coil, as recited in claims 57, 60-62, 70, and 84. Therefore, for at least the reasons presented above, the cited prior art also fails to teach or suggest the subject matter recited in claims 57, 60-62, 70, and 84, and all of the claims dependent thereon.

V. Conclusion

In view of the foregoing remarks, this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing the claims in condition for allowance. Applicants submit that the proposed amendments of claim 32 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were earlier claimed in claim 97. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicants respectfully point out that the final action by the Examiner presented some new arguments as to the application of the art against Applicants' invention. It is respectfully submitted that the entering of the Amendment would allow the Applicants to reply to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims. Applicants therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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